Clinical evaluation of indirect particle-filled composite resin CAD/CAM partial crowns after 24 months

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Abstract: PURPOSE: Resin-based CAD/CAM compound materials might be promising for single-tooth restorations. Insufficient clinical data are available for this new material class. The purpose of this study was to describe initial clinical in vivo results for indirect particle-filled composite resin CAD/CAM restorations after 24 months. MATERIALS AND METHODS: Indirect particle-filled composite resin restorations were fabricated with a CAD/CAM method (CEREC Bluecam intraoral scanner, CEREC MCXL milling unit) by calibrated dental students. Forty-two partial crown restorations were seated adhesively in 30 patients with caries lesions or insufficient restorations (baseline). Strict inclusion criteria were defined for the patient collective. Follow-up evaluation comprised 40 restorations after 12 months and 33 restorations after 24 months. Evaluation criteria were modified FDI criteria with grades (1) to (5). Rating with FDI criteria (5) was defined as clinical failure. Statistical analysis was performed with Wilcoxon-Test ($p < 0.05$). RESULTS: The success rate of indirect particle-filled composite resin CAD/CAM restorations after 12 months was 95.0% with two debondings observed. The cumulative success rate for indirect particle-filled composite resin CAD/CAM restorations after 24 months was 85.7% with two tooth fractures and one debonding. Statistically significant differences were found for baseline and 24-month follow-up evaluation for anatomic form and marginal adaptation criterion examined in respect to FDI criteria guidelines (Wilcoxon-Test, $p < 0.05$). CONCLUSIONS: This study demonstrates particle-filled composite resin CAD/CAM restorations having a clinical success rate of 85.7% after 24 months. Adhesive bonding procedures need to be ensured carefully. A longer clinical evaluation period is necessary to draw further conclusions.

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TITLE

Clinical Evaluation of Indirect Particle-Filled Composite Resin CAD/CAM Partial Crowns after 24 Months

RUNNING TITLE

Evaluation Lava Ultimate after 24 Months

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ABSTRACT

Purpose: Resin-based CAD/CAM compound materials might be promising for single-tooth restorations. Insufficient clinical data are available for this new material class. The purpose of this study was to describe initial clinical in vivo results for indirect particle-filled composite resin CAD/CAM restorations after 24 months.

Materials and Methods: Indirect particle-filled composite resin restorations were fabricated with a CAD/CAM method (CEREC Bluecam intraoral scanner, CEREC MCXL milling unit) by calibrated dental students. Forty-two partial crown restorations were seated adhesively in 30 patients with caries lesions or insufficient restorations (baseline). Strict inclusion criteria were defined for the patient collective. Follow-up evaluation comprised 40 restorations after 12 months and 33 restorations after 24 months. Evaluation criteria were modified FDI criteria with grades (1) to (5). Rating with FDI criteria (5) was defined as clinical failure. Statistical analysis was performed with Wilcoxon-Test ($p < 0.05$).

Results: The success rate of indirect particle-filled composite resin CAD/CAM restorations after 12 months was 95.0% with two debondings observed. The cumulative success rate for indirect particle-filled composite resin CAD/CAM restorations after 24 months was 85.7% with two tooth fractures and one debonding. Statistically significant differences were found for baseline and 24-month follow-up evaluation for anatomic form and marginal adaptation criterion examined in respect to FDI criteria guidelines (Wilcoxon-Test, $p < 0.05$).

Conclusions: This study demonstrates particle-filled composite resin CAD/CAM restorations having a clinical success rate of 85.7% after 24 months. Adhesive bonding procedures need to be ensured carefully. A longer clinical evaluation period is necessary to draw further conclusions.

KEYWORDS: Particle-filled composite resin; CAD/CAM; CEREC; clinical study; Lava Ultimate.

Composite resin materials have been shown to have a high clinical success rate in restorative therapy.[1,2] Clinical indications for composite resin materials are limited because of material characteristics such as polymerization shrinkage and abrasion coefficient.[3] Indirect restorations have been shown to strengthen the remaining tooth substance and might be preferable if the tooth defect exceeds a certain dimension.[4] Several material classes have been used for indirect restoration fabrication.[5] Ceramics are more brittle and more susceptible to fracture than composite resins if overload or inappropriate load is exerted.[6] Adhesive seating is mandatory for ceramic materials with flexural strengths below 200 MPa.[7] Resin-based CAD/CAM compound restorative materials might be promising. Initial results in our laboratories (not yet published) show that the minimum thickness of resin-based CAD/CAM restorations might be reduced. Compared to ceramics, resin-based compound materials showed fewer material fractures and a higher margin stability after milling.[6] The first resin-based composite material, Paradigm MZ 100 (3M ESPE; St. Paul, MN), was introduced for use in fabricating single-tooth CAD/CAM restorations in 2001.[8]

The resin-based CAD/CAM material Lava Ultimate (3M ESPE) was among the first compound CAD/CAM materials available for single-tooth restoration. The material consists of a polymeric composite framework with embedded ceramic particles. These particles make up to 80% of the material by weight and can be as small as 4 to 11 nm. The flexural strength of Lava Ultimate is reported to be 200 MPa.[9,10] At this moment, no clinical data are available for particle-filled composite resin CAD/CAM restorations. The aim of this study was to evaluate the clinical outcome of indirect particle-filled composite resin CAD/CAM restorations after 24 months.

MATERIALS AND METHODS

Ethical approval and recruitment criteria

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its amendments or comparable ethical standards. The study was performed as part of protocol number 490-13 accepted by the ethical committee of the Ludwig-Maximilians-University Munich.

Patients with decayed caries lesions or insufficient restorations were recruited from the daily patient collective of the Department of Restorative Dentistry and Periodontology of the Ludwig-Maximilians-University Munich. Strict inclusion criteria were defined for the patient collective. The inclusion and exclusion criteria are shown in Table 1. All patients gave written

consent for participation in the study. Thirty patients were included in the study. The distribution of gender was seventeen male and thirteen female patients. The patients' average age was 56.4 years (± 14.8 years SD). Good general health status (ASA-criteria 1) was mandatory. Forty-two indirect restorations were fabricated by calibrated dental students under strict supervision of an experienced dentist. Fifteen maxillary teeth and twenty-seven mandibular teeth were treated (29 molars, 13 premolars). Evaluation criteria in this study were modified FDI criteria.[11-14] Baseline evaluation was performed a day after restorations seating (baseline). Recall evaluation was performed after 12 months (follow-up 12M) and again after 24 months (follow-up 24M).

Clinical protocol

Prior to tooth preparation, local anesthesia (Ultracain D-S 2 %; Sanofi Aventis, Paris, France) was administered. The teeth were prepared according to guidelines for full ceramic preparation.[7] The preparation margins ended within the enamel or dentin. If the remaining wall thickness was below 1.5 mm after caries removal, shortening of the cusp in terms of a partial crown preparation was performed. Conventional full-arch impressions of the preparation were obtained with polyether material Impregum Penta (3M ESPE). Conventional impressions of the opposing arch were made with alginate material (Omnident Dental, Rodgau Nieder-Roden, Germany). Plaster stone casts were poured for both maxillary and mandibular arch with Type IV scannable gypsum (CEREC Stone BC; Dentsply Sirona, York, PA). Quadrant scans of the maxillary and mandibular cast were taken with the CEREC Bluecam (Dentsply Sirona) with a strictly observed scanning strategy.[15] Interim prostheses were provided for the prepared teeth (Luxatemp; DMG, Hamburg, Germany) and seated with RelyX Temp NE (3M ESPE). CAD design of final restorations was performed with CEREC CAD software (software v4.0.). Resin based particle-filled blocks were selected as restorative CAD/CAM material (Lava Ultimate) and milled with the CEREC MCXL milling unit (cylinder pointed bur 12 and step bur 12s, milling mode 'standard'). Forty-two partial crowns were fabricated. The post-processing method was a three-step extraoral polishing procedure (polishing set 4313B; Brasseler, Lemgo, Germany) using a standardized protocol (5000 - 6000 rpm, time per instrument: 30 seconds, water cooling 50 ml/min, light contact pressure).

The particle-filled composite resin restorations were seated adhesively. The luting surfaces of the restorations were airborne-particle abraded with Si-coated aluminum oxide (Cojet; 3M ESPE) (diameter ≤ 50 µm,

200 kPa). Restorations were cleaned with alcohol and air dried with oil- and water-free air. Silane (Espe-Sil; 3M ESPE) was applied to the restorations' luting surface for a period of at least 60 seconds prior to adhesive luting. The prepared teeth were isolated with rubber dam and etched with 37% phosphoric acid (application time: 30 seconds enamel, 15 seconds dentin). Syntac was used as adhesive bonding agent (application time: 15 seconds primer, 10 seconds adhesive, no light curing of Heliobond) with Variolink II high viscosity (Ivoclar Vivadent AG, Schaan, Lichtenstein) dual-polymerizing composite resin system. After any excess was removed, an oxygen layer inhibitor material was applied to the cementation interface (Airblock; Dentsply DeTrey, Konstanz, Germany). Luting composite resin was polymerized with a polymerization lamp (Satelec MiniLED; KaVo, Biberach, Germany) using 16 J/cm^2 from the occlusal, mesial, distal, buccal, and lingual aspects for 60 seconds each. The restoration margins were finished and the occlusal contacts were adjusted using fine diamond rotary instruments coupled with constant water-cooling. A three-step ceramic polishing kit (ceramic polishing set 4313B; Brasseler) was used for the final intraoral polishing procedure.

Evaluation criteria and statistical analysis

Evaluation criteria were modified FDI criteria.[11-14] The evaluation was performed a day after adhesive seating (baseline), at 12-month recall (follow-up 12M) and at 24-month recall (follow-up 24M). There were three evaluation categories (esthetics, function, biology) with each five sub-categories. From best to worst, the sub-categories were: (1) clinically excellent, (2) clinically good, (3) clinically sufficient, (4) clinically not sufficient but repairable, (5) clinically unacceptable. Evaluation with category (5) was rated as a clinical failure. A blinded, calibrated, and experienced dentist performed follow-up evaluation. Statistical analysis for baseline and follow-up criteria was performed with Wilcoxon-Test ($p < 0.05$) (SPSS; IBM, Chicago, ILI).

RESULTS

Evaluation after 12 months

Twenty-eight of 30 patients appeared for follow-up evaluation after 12 months, and 40 of 42 restorations could be evaluated (dropout rate 4.8%; follow-up rate 95.2%). Fifteen maxillary and 25 mandibular teeth (28 molars, 12 premolars) were evaluated. The distribution of gender was 15 male and 13 female patients. Two restorations were rated as a clinical failure as a result of debonding (failure rate 5.0%). Both restorations required refabrication. The success rate of indirect particle-filled composite resin CAD/CAM restorations after 12 months was 95.0%.

Evaluation after 24 months

Twenty-three of 28 patients appeared for follow-up evaluation after 24 months, and 33 of 38 restorations could be evaluated (dropout rate 13.2%, follow-up rate 86.8%). Thirteen maxillary and 20 mandibular teeth (22 molars, 11 premolars) were evaluated at follow-up. The distribution of gender was 14 male and 9 female patients. Three restorations were rated as a clinical failure. There was one debonding, and two tooth fractures. Restorations required refabrication. The cumulative success rate for indirect particle-filled composite resin CAD/CAM restorations after twenty-four months was 85.7%. Detailed results for baseline and 12M follow-up and 24M follow-up evaluation are summarized in Table 2.

Restoration failures

Two restorations clinically failed as a result of debonding at the 12- month evaluation. Both restorations required refabrication. Restoration failure (1) was the debonding of a partial crown on the mandibular first right molar. Debonding of the restoration occurred 2 months after insertion. Neither a fracture of tooth substance nor any other clinical abnormality could be detected. Percussion test was negative. The tooth surface of the prepared tooth was covered completely with luting composite (Figs 1, 2). After photographic documentation, the composite resin was carefully removed from the preparation, and a new partial crown was fabricated with Lava Ultimate and CEREC. Restoration failure (2) was the debonding of a restoration on the maxillary first left molar. Debonding of the restoration occurred a month after insertion. The patient instantly showed up in person at the clinic. There were no cracks within the tooth substance. The percussion test of the vital tooth was negative. The tooth surface was covered with luting composite, whereas small areas no longer showed adhesive sealing. The patient agreed with the fabrication of a new partial crown with Lava Ultimate and CEREC. The remaining composite was carefully removed and the new restoration was adhesively seated according to the standardized protocol.

Three restorations clinically failed at the 24-month evaluation. Restoration failure (3) was the fracture of the mesio-oral cusp of the maxillary left first molar. The fracture occurred 13 months after insertion. No other clinical abnormality could be detected. Percussion test was negative. The tooth had been treated with a root canal treatment prior to restoration. The fracture line was located directly epigingival from the mesial to the distal aspect. No other cracks could be detected within the surrounding tooth substance (Fig 3). A new particle-filled composite resin partial crown restoration was fabricated and seated adhesively. Restoration failure (4) was a debonding of a partial crown restoration of the mandibular second right molar after 22 months. The tooth surface was covered with luting composite (Fig 4). Percussion test of the vital tooth was negative. The patient agreed with the refabrication of a new particle-filled composite resin partial crown after the remaining luting composite had

been removed carefully. Restoration failure (5) was a probable tooth fracture at the oral aspect of the upper right first molar (Fig 5). Percussion test of the vital tooth was negative. The patient preferred the refabrication of a new particle-filled composite resin crown.

Statistical Analysis

The clinical success rate of indirect particle-filled composite resin restorations after 12 months was 95.0% and 85.7% after 24 months. Statistical analysis between baseline and follow-up criteria using Wilcoxon-Test ($p < 0.05$) revealed statistically significant differences for anatomic form criterion ($p = 0.028$) and marginal adaptation criterion ($p = 0.042$) for groups 0M (baseline) and 24M (24month follow-up). There were no statistically significant differences for all criteria for groups 0M (baseline) and 12M (12-month follow-up).

DISCUSSION

The aim of this study was to evaluate the clinical outcome of indirect particle-filled composite resin CAD/CAM restorations after 24 months. The clinical success rate of indirect Lava Ultimate restorations after 12 months was 95.0% and 85.7% after 24 months. Five clinical failures for Lava Ultimate partial crown restorations occurred after 24 months (3 debondings, 2 fractures within the tooth substance). Several aspects should be discussed.

First, there is no typical control group. This study is a prospective observation study without a control group. Because the particle-filled composite resin material is one of the first representatives of a new class of CAD/CAM materials, no comparable CAD/CAM restorative material was available at the moment the study was conducted. In this study, instead of adding more control groups with different material characteristics, the clinical behavior of the new material class particle-filled composite resin was the main focus of interest.

Several published studies refer to the clinical survival of CAD/CAM fabricated CEREC restorations.[16-18] Results are available both for ceramic and composite materials. Fasbinder et al report that resin-based Paradigm MZ 100 composite inlays performed as well as Vita Mark II ceramic inlays at 3 years in all categories, with clinical advantages noted in fracture resistance and better color match to the tooth.[18] Reiss showed high clinical success rates for indirect ceramic inlays fabricated with the CEREC system with 84.4% after 18 years.[19] In a systematic review of clinical studies for CEREC ceramic inlays, Martin and Jedynakiewicz reported a mean survival rate of 97.4% after 4 years.[20] Clinical data for partial crown ceramic restorations fabricated with the CEREC system are scarce.[21,22] In this study partial crown restorations fabricated from particle-filled resin CAD/CAM blocks were investigated. The survival rate after 24 months was 85.7%; however, a longer clinical observation period is mandatory to draw further conclusions.

The specific material characteristics of particle-filled composite resin restorations should be discussed. In this study, no chipping fracture of particle-filled composite resin restorations could be observed. A complex, cohesive fracture of the restoration material including a fracture of the tooth substance could not be observed. These observations might refer to the resilient material characteristics of a compound material such as Lava Ultimate. Compound materials might thus be advantageous for postendodontic restorative treatment. Restorations on endodontically treated teeth are reported to be more susceptible to fracture, as pulpal proprioceptive mechanisms are missing.[23] Compound materials might buffer occlusal overloads and reduce chipping failures; however, the resilient characteristics of composite CAD/CAM materials are discussed controversially in literature. Duan and Griggs investigated the effect of elasticity on the stress distribution in CAD/CAM-fabricated crowns made of ceramics and composite materials.[24] Based on the results found in their study, Duan and Griggs suggested that composite crowns would probably not be indicated for patients known to exhibit bruxism because of the increased stress that the composite material developed under lateral loading.[24] A high elasticity of a restoration material may result in stress on the phase boundary of the luting interface and may result in debonding. The fact that the manufacturer recently has limited the clinical indication for Lava Ultimate restorations to not use the material for crowns and to prepare the tooth for maximum mechanical retention appears to be also relevant for this aspect.

The tooth fracture observed in this study was related to a partial crown preparation where a small cusp had not been included in the preparation. The authors assume that a prior micro crack had not been detected prior to the restoration's seating.

The bonding strength of the particle-filled composite resin material and its clinical relevance needs to be discussed. Frankenberger et al recently published in vitro results for the bonding strength of different CAD/CAM materials including Lava Ultimate using a microtensile bond strength approach.[25] The highest bonding strength for Lava Ultimate restorations was found to be 17.9 ± 4.5 MPa if sandblasting of the restoration was performed prior to its adhesive seating. Compared to conventional ceramics these values are low. Lithium-disilicate ceramics such as e.max CAD were found to have a microtensile bond strength of 26.3 ± 7.7 MPa if HF and silane were applied to the restoration prior to its adhesive seating. For compound materials, no ceramic framework is available for bonding. Particle-filled composite resin materials have a limited bonding strength and might thus be more susceptible to bonding failure if the bonding protocol is not respected exactly. The fact that three out of the five restorations failures occurred in this study were related to debonding supports this theory from the clinical point of view. In fact, for each debonding failure reported in this study, the luting composite covered the tooth surface. The compound luting resin composite and restoration material might have been the weak spot. Mandatory observance

of the manufacturer's instructions is recommended, and strict moisture control is mandatory while adhesively seating particle-filled composite resin restorations.

Compound materials, such as particle-filled composite resin, might be advantageous because of their post-processing procedure. The post-processing procedure used in this study was a three-step polishing procedure. The surface gloss was stable over the period of 12 months; however, after 24 months significant differences could be observed for the surface gloss criterion. These findings are in accordance with recently published literature. Koizumi et al reported that the surface roughness and gloss of CAD/CAM resin composite might be altered by external manipulations such as toothbrush abrasion.[26]

Particle-filled composite resin materials seem to be advantageous in terms of wear and abrasion. After 12 months only minimal abrasion occurred, corresponding to 100% of the cases to the physiological wear of enamel. After 24 months no significant differences could be detected for wear criterion. The clinical findings support the abrasion findings for compound CAD/CAM materials recently described by Mörmann et al in vitro.[6] In this study, two-body wear results for Lava Ultimate CAD/CAM material were found to be 48.1 µm on the contact area and 25.3 µm on the enamel antagonist. The control group enamel was found to have a loss of 42.1 µm on the contact area and 54.5 µm of the enamel antagonist. Particle-filled composite resin might thus have enamel-like abrasion characteristics preserving the natural dentition. The results described by Mörmann et al are in accordance with the clinical findings of this study.

CONCLUSION

Particle-filled composite resin CAD/CAM materials might be promising for single-tooth restorations because of their advantageous material characteristics; however, mandatory observance of the manufacturer´s instructions is recommended while adhesively seating particle-filled composite resin restorations. A longer clinical observation period is necessary to draw further conclusions.

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Table 1: Inclusion and exclusion criteria for patient recruitment; in total 30 patients participated (13 female patients, 17 male patients, average age 56.4 ± 14.8 years)

Inclusion criteria	Exclusion criteria
Oro-vestibular defect size: >50% of tooth cusp distance	Oro-vestibular defect size: <50% of tooth cusp distance
Complete or partial reconstruction of tooth cusp	Need of direct/indirect capping prior to reconstruction
Molars or premolars with antagonist	Patient suffering from bruxism/CMD

Table 2: Clinical evaluation of indirect particle-filled composite resin CAD/CAM restorations; esthetics, functional, and biological criteria at baseline evaluation (0M), 12-month evaluation (12M), 24-month evaluation (24M); FDI criteria from best to worst (1) - (5).

	Surface gloss			**Surface/Marginal staining**			**Color match**			**Anatomic form**			
	0M	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	
(1)	27	24	15	-	30	12	24	18	4	35	31	4	**Esthetic criteria**
(2)	15	14	15	-	8	16	14	16	20	5	5	24	
(3)	0	0	0	-	0	2	4	4	6	2	2	2	
(4)	0	0	0	-	0	0	0	0	0	0	0	0	
(5)	0	0	0	-	0	0	0	0	0	0	0	0	

	Fracture/Retention			**Marginal adaptation**			**Wear**			**Contact point**			
	0M	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	
(1)	42	38	30	34	30	25	-	34	17	37	33	9	**Functional criteria**
(2)	0	0	0	8	8	4	-	2	12	0	0	9	
(3)	0	0	0	0	0	1	-	2	1	1	1	11	
(4)	0	0	0	0	0	0	-	0	0	4	4	1	
(5)	0	2	1	0	0	0	-	0	0	0	0	0	

	Postoperative hypersensitivity			**Caries/Erosion/ Abfraction**			**Tooth integrity**			**Periodontal response**			
	0M	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	**0M**	**12M**	**24M**	
(1)	-	18	17	-	38	28	42	38	30	-	32	30	**Biological criteria**
(2)	-	0	0	-	0	0	0	0	0	-	1	0	
(3)	-	0	0	-	0	2	0	0	0	-	4	0	
(4)	-	0	0	-	0	0	0	0	1	-	1	0	
(5)	-	0	0	-	0	0	0	0	1	-	0	0	

Figure 1: Clinical failure of particle-filled composite resin partial crown after 2 months; lower first right molar; debonding of restoration: FDI criterion fracture/retention (5).

Figure 2: Oral view of debonding failure (1); tooth surface covered completely with luting composite.

Figure 3: Clinical failure of particle-filled composite resin partial crown after 13months; upper first left molar; fracture of mesio-oral cusp: FDI criterion tooth integrity (5).

Figure 4: Clinical failure of particle-filled composite resin partial crown after 22 months; lower second right molar; debonding of restoration: FDI criterion fracture/retention (5).

Figure 5: Clinical failure of particle-filled composite resin partial crown detected at 24-month recall; upper right first molar; fracure of oral aspect: FDI criterion tooth integrity (4).